Hamilton Thorne Research
100 Cummings Center, 102 C
181 Elliott Street
Beverly, Massachusetts 01915

MAR 1 3 2002

K012805

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. **Submitter's name:** Hamilton Thorne Research
   Submitter's address: 100 Cummings Center, Suite 102-C
   Beverly, MA 01915
   Submitter's telephone No.: 978 -921-2050

   Contact Person: Diarmaid Douglas-Hamilton,
   Vice President, Research and Development

   Date Summary Prepared: August 17, 2001

2. **Trade or proprietary name:** AutoMARQER™
   Common or usual name: Differential spectrophotometer/reflectometer
   Classification name: Hematology
   Class: II

3. **Legally marketed predicate device:** IVOS Sperm analysis system
   [Hamilton Thorne Research (K920719, SE 6/29/92)]

4. **Subject device description:**

   The AutoMARQER™ functions as a differential spectrophotometer / reflectometer, using MARQ™ Plus Test Kits* for sperm analysis.

   The AutoMARQER conducts sequential measurement operations on a specimen introduced into the instrument on a special MARQ™ Plus Test Kit cassette designed for use with the AutoMARQER.

   When using the FertilMARQ Plus Test Kit,* the AutoMARQER measures sperm concentration, motility and velocity. The AutoMARQER performs as a spectrophotometer when measuring specimen concentration. When measuring motility and velocity, it measures light scatter that occurs as sperm intercept its laser beam. It measures number of sperm in a beam directly by counting sperm cells crossing the beam and determines their velocity by the length of beam passage. Since the beam diameter is known, the crossing time gives the sperm velocity

   * *Embryotech Laboratories, Wilmington, MA, commercializes the MARQ™ Plus Test.*

5. **Subject device intended use**:

The AutoMARQER™ is a differential spectrophotometer/reflectometer for sperm analysis and quantification, using MARQ™ Plus Test Kits.

6. **Performance data**:

Equivalent results are obtained on semen samples analyzed by both the AutoMARQER™ and the IVOS™ Sperm analysis system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 3 2002

Mr. Diarmaid Douglas-Hamilton
Vice President, Research and Development
Hamilton Thorne Research
100 Cummings Center, Suite 102-C
Beverly, Massachusetts 01915

Re: k012805
Trade/Device Name: AutoMARQER™
Regulation Number: 21 CFR § 864.5200
Regulation Name: Automated Cell Counter
Regulatory Class: II
Product Code: GKL, MNA
Dated: January 12, 2002
Received: January 25, 2002

Dear Mr. Douglas-Hamilton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. Indications for use of the Device

510(k) Number): [To be assigned]

Device Name: AutoMARQER™

Indications for Use:

The AutoMARQER™ is a differential spectrophotometer/reflectometer for sperm analysis and quantification, using MARQ™ Plus Test Kits.

(Please do not write below this line—continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012805

Prescription Use X **or Over-the-Counter Use** ___

(Per 21 CFR 801.109) (Optional Format 1-2-96)